Exhibit J

Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study

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PURPOSE: To assess the technical success and safety for retrieval of the G2 filter.

MATERIALS AND METHODS: The authors performed a prospective, multicenter study of 100 patients with temporary indication for caval interruption. Patients were enrolled consecutively between December 2005 and July 2006. There were 67 men and 33 women with a mean age of 52.1 years (range, 19–82 years). Indications for filter placement were trauma (n = 56), perioperative risk (n = 16), and medical indications (n = 28). Forty-two patients had venous thromboembolism at filter placement. Fifty-eight filters were placed prophylactically.

RESULTS: Retrieval was attempted in 61 patients. Fifty-eight of the 61 filters (95%) were successfully retrieved after a mean dwell time of 140 days (range, 5–300 days). In all failed retrievals, the filter tip was against the caval wall. There was no difference in dwell times between successful and unsuccessful retrievals. Although there were no cases of cranial migration, caudal migrations were observed in 12% of cases (10 of 85 patients with a complete data set). Other device-related complications included filter fracture (1/85, 1.2%), filter tilt of more than 15° (15/85, 18%), and leg penetration (16/61, 26%). The recurrent pulmonary embolism (PE) rate was 2%, with no PE in the 30-day period after filter retrieval.

CONCLUSIONS: Retrieval of the Recovery G2 filter was safe and successful in most patients. Caudal migration was observed as an unexpected phenomenon.

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Abbreviations: DVT = deep venous thrombosis, IVC = inferior vena cava, PE = pulmonary embolism, VTE = venous thromboembolism

VENOUS thromboembolism (VTE) is a leading cause of death in hospitalized patients (1–3). Anticoagulation is the standard therapy for VTE, but in certain cases anticoagulation may be contraindicated for short- or long-term VTE therapy.

Inferior vena cava (IVC) filters have been shown to successfully prevent pulmonary embolism (PE) (4). However, although IVC filters decrease the risk of PE in the short term, they are associated with a higher incidence of deep vein thrombosis (DVT) after 2 and 8 years (5,6). The observation of Decousus et al (5) stimulated the idea of optional filters. Optional filters are permanent filters with the "option" to be retrieved if they are no longer clinically needed to avoid possible long-term adverse effects of permanent filters.

The G2 filter (Bard Peripheral Vascular, Tempe, Arizona) is a second-generation optional filter with an updated design compared to the original Recovery filter (Bard Peripheral Vascular). The permanent use of the G2 filter for the prevention of PE was previously reported (7–10). The purpose of this study was to assess the retrievability of the G2 filter.

MATERIALS AND METHODS

Study Design

This prospective single-arm multicenter Investigational Device Exemption clinical study, sponsored by Bard Peripheral, was conducted in accor-

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dance with the SIR reporting standards (11) at 11 sites within the United States: Brigham & Women's Hospital, Boston, Massachusetts; Inova Fairfax Hospital, Falls Church, Virginia; University of Florida, Gainesville, Florida; Dotter Interventional Institute-OHSU, Portland, Oregon; Cleveland Clinic, Cleveland, Ohio; Mayo Clinic, Rochester, Minnesota; Penn State, Hershey, Pennsylvania; Hartford Hospital, Hartford, Connecticut; Froedtert Memorial Lutheran Hospital, Milwaukee, Wisconsin; Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; and George Washington University Medical Center, Washington, DC.

Patients were consecutively enrolled from December 2005 through July 2006. All patients were informed of the risks and benefits of participating in the study and gave written informed consent to participate before enrollment. The protocol was approved by the institutional review board at each study site, and all study procedures were conducted in accordance with Good Clinical Practices.

Study procedures included ultrasonographic (US) screening for a patent jugular vein to be used for future filter retrieval, placement of the study filter, and conventional radiographic examination of the abdomen in full expiration (anteroposterior, lateral, and bilateral anterior-oblique projections) within 48 hours after filter placement. If the filter was not retrieved, a phone assessment was conducted at 3 months and a clinic visit at 6 months, including repeat conventional radiography.

The indication for filter retrieval was discussed with the referring medical team. Filter retrieval was performed if there was no longer an increased risk for PE and/or no longer a contraindication to anticoagulation. Vascular US of the deep vein system was performed beforehand in patients with prophylactic filter placement. If no DVT was found, no further anticoagulation was undertaken. If a DVT was found in these patients and in all patients with known DVT or PE, a 6-month course of anticoagulation was carried out. A cavogram with iodinated contrast medium was obtained before and after filter retrieval in all patients. In addition, a follow-up clinic visit was required 1 month after retrieval.

Patient Population

One hundred patients (67 men, 33 women) were included in the study. The mean patient age was 52.1 years (range, 19–82 years). Patients considered for inclusion in the study were temporarily at increased risk for PE with a need for caval interruption because of a contraindication of anticoagulation. The indication for filter placement is summarized in the **Table**. Additional study requirements included an estimated life expectancy of more than 6 months, a normal right-sided IVC with a diameter less than 28 mm, and a serum creatinine level of less than 2.0 mg/dL (176.8 μmol/L) for safe application of iodinated contrast medium.

Forty-two patients presented with VTE at filter placement: 18 had DVT only, 10 had PE only, and 14 had both DVT and PE. Of the 58 patients without VTE, 10 had a history (>3 months) of VTE.

Indications for Filter Placement

Indication for Filter Placement	No. of Patients (n = 100)
Trauma*	56 (56%)
Surgery (within 1 mo)†	16 (16%)
Nonsurgical treatment‡	28 (28%)

* The trauma category includes spine, abdominal, long bone, pelvic, thoracic, and head trauma.
† The surgical category includes surgical patients with a history of or active VTE at the time of filter placement, including those with a primary diagnosis that was bariatric, gastrointestinal, orthopedic (joint replacement, spine), neurosurgical (intracranial, spine), or related to a gynecologic procedure.
‡ The nonsurgical treatment category includes patients with a medical condition preventing safe anticoagulation, including those with a primary diagnosis that was related to cancer (with or without metastases), a gynecologic disorder, hypercoagulopathy (without malignancy), morbid obesity, or stroke (within 6 months).

Device

The devices used in this study were the G2 filter (**Figure**) and the Recovery Cone Removal System (Bard Peripheral Vascular). The filter consists of 12 shape-memory nitinol wires emanating from a central nitinol sleeve. The wires form two levels of filtration, with the legs (leg span, 40 mm; overall height, 39 mm) providing the lower level of filtration and the arms (arm length, 18.5 mm; span, 33 mm) providing the upper level of filtration. The nitinol filter was designed for use in IVCs with diameters less than or equal to 28 mm. The insertion and retrieval techniques were previously described by Oliva et al (12).

Outcome

The primary objective of the study was to assess the technical and clinical success of the G2 filter retrieval, including adverse events within 30 days after retrieval. In addition, we evaluated the overall clinical experience, as assessed by filter migration and filter fracture and relevant placement procedural parameters and outcomes.

Filter migration was defined as a change in filter position compared to its deployed position (either cranial or caudal) of more than 2 cm as documented with plain radiography or venography. Filter fracture was defined as any loss of structural integrity (ie, breakage or separation) of the filter documented at imaging. Filter penetration/protrusion was defined as penetration of a filter leg or arm of more than 3 mm outside the IVC measured at venography according to the American College of Radiology Practice Guidelines (13). During the clinical visit 6 months after filter placement or 1 month after filter retrieval, a history and physical examination was performed, focusing on symptoms of PE (shortness of breath) and DVT (leg swelling, leg pain).

RESULTS

Filter Placement

All 100 G2 filters were deployed successfully. For access, the right common femoral vein was used 90 times, and the left common femoral vein was accessed 10 times.

The mean fluoroscopy time was 3.2 minutes (range, 0.4–33.6 minutes). The mean IVC diameter (± standard deviation) was 20.5 mm ± 3.4 (range, 12–28 mm). Two filters were noted to

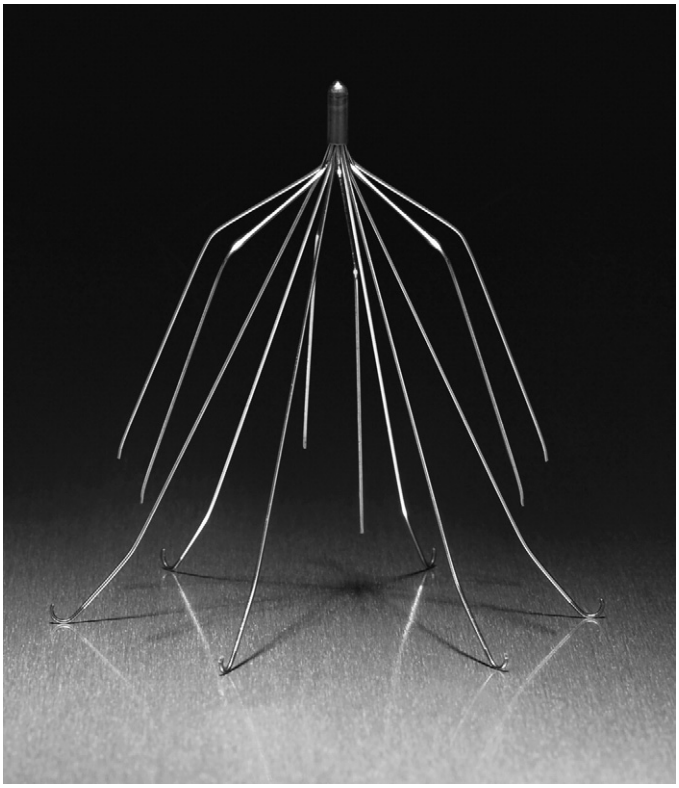

Figure. G2 filter. Compared with the original Recovery filter, the arms are longer and the legs wider. The welding at the tip was also changed.

have had a tilt of more than 15° immediately following placement. Both filters were placed from the right common femoral vein, and no attempt was made to straighten the filters. All imaging studies were assessed by the site investigators.

Postplacement Procedure Follow-up

All patients enrolled in the study were to be followed up to 6 months after filter placement or to 1 month after filter retrieval, whichever came first. A phone call was placed 3 months after filter placement to assess filter retrieval status, current medications, and adverse events. Office visits were scheduled at 6 months after placement if the filter had not been retrieved. A physical examination, current medication assessment, adverse event assessment, and follow-up imaging were completed (supine anteroposterior abdominal radiography in anteroposterior and lateral projections at full expiration and posteroanterior digital spot radiography centered on the filter). If the physician determined that the filter continued to be clinically indicated, the device could be left in place permanently. At study completion, 83 of the 100 patients enrolled had a complete data set for evaluation (see Final Follow-up).

Filter Retrieval

Retrieval was attempted in 61 patients. The right internal jugular vein was used for access in all cases. In 58 of the 61 patients, retrieval was successful. All study retrieval procedures were performed by using standard Recovery cone technique. In three cases, retrieval failed because the filter tip could not be engaged with the cone as the filter tip was embedded in the IVC wall.

The mean fluoroscopy time for the attempted filter retrievals,, as recorded in 59 of the 61 patients, was 7.4 minutes ± 10.5 (range, 1.4–59.8 minutes). The mean fluoroscopy time for successful retrieval procedures (56/58 recorded values) was 6.3 minutes ± 8.5 (range, 1.4–59.63 minutes). The mean fluoroscopy time of unsuccessful retrieval attempts was 27.8 minutes (range, 2.4–48.3 minutes). The significantly longer fluoroscopy times for the unsuccessful retrievals are indicative of more difficulties during retrieval attempt ($P = .03$).

The mean filter dwell time in the 61 patients in whom retrieval was attempted was 138 days (range, 5–300 days). The mean dwell time in patients with successfully retrieved filters was 140 days (range, 5–300 days). The mean dwell time in patients with failed retrievals was 107 days (range, 92–134 days). There was no statistically significant difference between the dwell times of successful versus unsuccessful retrievals ($P = .11$).

Venography was normal in 52 of the 61 attempted retrievals (in one case, venograms were lost). In eight cases, venograms were reported as abnormal. Four venograms showed a small thrombus in the filter. In three cases, a stenosis was noted at the filter level of the IVC before retrieval and in two cases there was a stenosis after retrieval secondary to difficulties during filter retrieval. One stenosis was measured at more than 50%; however, there were no related clinical sequelae noted at the 1-month follow-up visit. In one case, both a stenosis of the IVC and a thrombus in the filter was documented.

Final Follow-up

Overall, 83 of 100 patients had a complete data set either with successful retrieval or observation for 6 months. Four patients completed all clinical evaluations but were lacking final imaging. Fifty-eight of the 61 attempted filter retrievals were successful. As previously discussed, three filter retrieval attempts were unsuccessful. Fifty-six of the 58 patients completed 1-month follow-up after retrieval; two patients were lost to follow-up. A total of 42 filters were not retrieved. No retrieval attempt was undertaken in 39 patients. Thirty-one of the 42 patients in whom filters were not retrieved completed the 6-month follow-up. However, as mentioned above, the final imaging data set was not available in four patients. Of the 11 patients who did not complete follow-up, six died, three withdrew consent, and two were lost to follow-up as previously discussed. Six deaths were reported between 22 and 100 days after filter placement (mean, 60.6 days). All were due to

pre-existing conditions (colon cancer, cardiac arrest, myocardial infarction, chronic obstructive pulmonary disease, pneumonia, and chondrosarcoma) and were not related to the study device, placement procedure, or retrieval procedure.

During the study, two symptomatic PE were recorded. Both PE occurred with the filter in place. No PE was noted during the 1-month observation period after the filter was removed. No new symptomatic DVT was noted during the study period.

Procedure-related Complications

One hundred filters were successfully deployed in 100 patients. There were four procedure-related complications during the study: three complications occurred during placement and one complication occurred during retrieval. One patient experienced an allergic skin reaction following access site preparation during both implantation and retrieval. One patient had acute renal failure secondary to multiple, same-day contrast studies and one had a hematoma related to device placement; however, all complications were resolved with no clinical sequelae.

Device-related Complications

Migration.—Ten filter migrations of more than 2 cm occurred in the 85 patients (12%) who were assessed for this category at a mean follow-up of 155 days (range, 5–323 days). The mean migration distance observed for the 10 migrated filters was 2.7 cm (range, 2.0–4.1cm). The 85 filter images analyzed for this endpoint include 58 filters imaged at retrieval and 27 nonretrieved filters imaged at 6 months. All migrations occurred toward the feet (ie, caudal migration). Five of these migrated filters were retrieved successfully and two remained in place after an unsuccessful retrieval attempt. In three cases, no retrieval attempt was performed.

Filter fracture.—One filter fracture occurred in the 85 assessed devices (1.2%). Preretrieval venography performed on day 92 revealed a mild filter tilt with a fractured strut external to the IVC. One arm and one leg were observed outside the IVC. A retrieval attempt was unsuccessful secondary to the apex being embedded in the IVC wall. Nevertheless, this patient remained asymptomatic and without symptoms of PE during final follow-up through day 209.

Filter tilt.—Overall, 15 of the 85 filters (18%) with assessable images showed a tilt of more than 15°. Two previously mentioned filters tilted during placement; the remaining 13 developed tilt during follow-up. Of the 15 tilted filters, 10 were removed successfully and three could not be removed. In two cases, no retrieval attempt was performed. No PE or other adverse event occurred in this group.

Filter penetration.—Assessment of filter penetration was only possible in the 61 patients who underwent venography before filter retrieval. Sixteen of the 61 patients (26%) showed a filter leg or arm penetrated more than 3 mm outside the IVC. Of these 16 patients, 14 had undergone a successful retrieval. Fifteen of 16 patients with penetration were asymptomatic, and one patient reported back pain that was relieved following filter retrieval.

Complication relationship.—The study data show a significant relationship between tilt or more than 15° and migration ($P < .001$); however, there is no statistical evidence that either migration or tilt is related to penetration.

DISCUSSION

In the present study, a relatively high percentage of retrieval attempts were undertaken (61/100). This is similar to that performed in other trials—including the studies by Ray et al (14) (47.7%), Keller et al (15) (49%, 70%), and Wicky et al (16) (67%)—and substantially higher than the retrieval rate in a clinical setup reported by Grande et al (17) (14%). This observation underlines again the importance of an organized follow-up in patients with optional filters.

The retrieval success of the G2 filter in our multicenter study was good, with a technical success rate of 95% (58/61). In a single-center study, Oliva et al (12) had an even higher retrieval rate (100%) for the G2 filter. The retrieval rates for the G2 are similar to those reported for other filter types: The rates for the Günther Tulip filter, the original Recovery filter, the ALN filter (ALN Implants, Chirurgicaux, Ghisonaccia, France), and the OptEase filter (Cordis, Bridgewater, New Jersey) varied from 76% to 98%; 82% to 100%, 50% to 100%, and 91% to 100%, respectively (14,15,17–20). The fluoroscopy times for filter retrieval (mean, 7.4 minutes; range, 1.4–59.8 minutes) were similar to those of other reports with the Günther Tulip filter (Wicky et al [16] reported a mean fluoroscopy time of 6.61 minutes and de Gregorio et al [21] reported a mean fluoroscopy time of 4.4 minutes) and the original Recovery filter (Binkert et al [9] reported a mean fluoroscopy time of 5.8 minutes).

The retrieval rates may have been even higher had alternative retrieval techniques, such as the loop-snare-technique, been applied (22). However, during the present study only the standard retrieval with the Recovery cone was allowed. Retrieval failures were all due to tilted filters with the tips embedded in the IVC wall and were unrelated to dwell time. The mean dwell time in our study was 140 days, which is higher than that reported in most published studies of other filter types—with reported dwell times between 8 and 28 days (15,16,23). The results from the present study suggest that the G2 may likely be retrievable even after 6 months, similar to the reported results with the original Recovery filter (9).

Filter migration is likely the most concerning filter-related complication. Cranial migration was not seen with the G2 filter in our study. Two case reports described migration of a G2 into the right ventricle (24,25). In both case reports the G2 did not open properly and legs entangled within each other, allowing the filter to migrate cranially. It seems that it is important to check for appropriate leg opening of the G2 after placement. Caudal migration, however, was observed in 10 cases in our study (12%). This is a rare phenomenon with a yet unclear mechanism. There is one letter reporting a caudal migration of a G2 filter during carbon dioxide venography (26). The authors hypothesized that caudal filter displacement was due to rapid IVC diameter expansion caudal to the filter caused by carbon dioxide injection. No carbon dioxide was used in the present study, but it is possible that other abrupt changes of the IVC diameter led to caudal migration. The mechanism of caudal migration remains unclear and warrants further investigation. However, the caudal migration of the G2 did not cause any clinical problems in our study.

The frequency of filter fracture and penetration has been reduced compared to original Recovery filter. In our study only one filter fracture (1.2%) was observed. Another study with the G2 reported no fracture (0/51) (12). These rates compare favorably with the reported fracture rate of 7.5% for the original Recovery filter (19). The penetration rate for a filter leg outside the IVC was also reduced—from the reported 62% for the original Recovery filter (19) to 26.2% in our study and to 18% of another study looking at the G2 (12).

The Recovery G2 filter provided a protection against PE in our study. We encountered two PE (2%), which is well within the 5% threshold of the American College of Radiology guidelines and comparable with reported rates of other studies (Grande et al [17%], 2.8%; Ray et al [14], 5%; Keller et al [15], 1.2%; Mismetti et al [18], 2.4%; and Neuerburg et al [27], 2.5%). Importantly, there was no additional PE during the 30-day follow-up after filter retrieval and no new symptomatic DVT caused by the study filter.

The present study has some limitations. The focus was on the technical aspect of the G2 filter. Inclusion criteria to enter the study were quite open, which explains the heterogeneous patient population. Clinical follow-up was performed 6 months after placement and/or 1 month after retrieval. However, during these visits the focus was on detecting clinically significant DVT and/or PE. The venous system was not examined with US for patency or insufficiency. Imaging was performed according to a defined schedule and technique but without a core laboratory for interpretation.

In conclusion, the Recovery G2 filter shows filtration properties that meet the SIR guidelines (28) and which are comparable to other filters. Retrievals were possible after dwell times up to 300 days, similar to the original reported long dwell times of the original Recovery filter. Compared to the original Recovery filter, the new design of the G2 filter showed a decrease in filter fracture and penetration rates. With the adjusted design, cranial migration was successfully avoided in the present study; however, caudal migration of the filter was observed in 12% of cases. The mechanism and the clinical effect of caudal migration warrant further investigation.

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